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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------|
| 10/763,974 | 01/22/2004 | Hassan Pajouhesh | 381092001600 | 7894 |
| 25225 7590 01/24/2007 MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040 | | | EXAMINER KOSACK, JOSEPH R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1626 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 01/24/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/763,974 | Applicant(s) PAJOUHESH ET AL. | |
| | Examiner Joseph Kosack | Art Unit 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-23 are pending in the instant application.

Amendments

The amendment filed on November 6, 2006 has been acknowledged and has been entered into the application file. Claims 21-23 are added and claims 21-23 (in part) are withdrawn as being drawn to non-elected subject matter.

Previous Claim Objections

Claims 1-17 were objected to in the previous action for containing elected and non-elected subject matter. The non-elected subject matter has not been cancelled yet, therefore the objection stands.

Previous Claim Rejections - 35 USC § 112

Claims 1-14 and 16 were rejected in the previous action under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Applicant has not addressed this rejection fully, therefore the rejection stands.

Claims 1-14 and 16 were rejected in the previous action under 35 U.S.C. 112, second paragraph as being indefinite. Applicant has replaced the indefinite term "noninterfering substituent" with the definition from the specification, and the rejection is withdrawn.

Previous Claim Rejections - 35 USC § 102

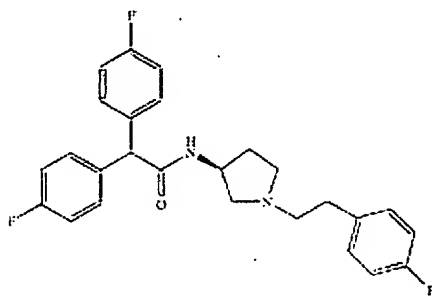
Claims 1-14 and 16 were rejected in the previous action under 35 U.S.C. 102(b) as being anticipated by Kuroita et al. (USPN 6,468,998). Applicant has amended the

claims on November 6, 2006 to proviso out the species, therefore the rejection is withdrawn.

Previous Claim Rejections - 35 USC § 103

Claims 1-17 were rejected in the previous action under 35 U.S.C. 103(a) as being unpatentable over Kuroita et al. (USPN 6,468,998). Applicant has traversed the rejection on the grounds that the disclosed species do not teach compounds that meet the new proviso in claim 1, that the instant claims are non-obvious over Kuroita et al. following an *In re Baird* analysis, and that there is no motivation to make those compounds.

The Examiner respectfully disagrees. *In re Baird* states that, "Given the vast number of diphenols encompassed by the generic diphenol formula in Knapp, and the fact that the diphenols that Knapp specifically discloses to be "typical," "preferred," and "optimum" *are different from and more complex than* bisphenol A, we conclude that Knapp does not teach or fairly suggest the selection of bisphenol A." (emphasis added) In the instant case, the claimed compounds are *not* more complex than those proposed



by Kuroita et al. One species in particular, claimed compounds where n is 0, W is L²-A³, L¹ is C(O), X¹ is CR³, L² is CH₂CH₂, A¹, A², and A³ are 4-fluorophenyl, and R¹, R², and R³ are hydrogen. See Example 67,

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column 30, lines 54-61, and the structure on column 44, lines 1-17. The only difference that is required to meet the scope of claim 1 is for the linking group to be extended or contracted, (L^2 in the instant case and D in Kuroita et al.) to overcome the new proviso:

and with the further proviso that L^1 must contain at least three linking atoms if X^1 is CH and W is L^2-A^3 , wherein L^2 contains two linking atoms and A^3 represents optionally substituted phenyl.

Since Kuroita et al. defines the D group to be :

D is optionally substituted linear or branched alkylene having 1 to 8 carbon atoms, and when D is branched alkylene, the carbon atom in the branched chain is optionally bonded further to Ar to form 4- to 8-membered ring, and

one of skill in the art would take the compound cited above, have motivation to use a different linking group between the para-fluorophenyl and the pyrrolidine nitrogen, and would have a reasonable expectation of success that the compounds will still antagonize 5-HT₂ to treat glaucoma and other ailments. See column 4, lines 38-43 and column 17, lines 51-63. Therefore, since only one group needs to be modified to take a disclosed species of Kuroita et al to generate a compound of the instant claims, and that modification is sufficiently suggested within the reference, one of ordinary skill would have motivation to make the change to practice fully the invention of Kuroita et al. The rejection is maintained.

Previous Double Patenting Rejections

Claims 1-17 were rejected in the previous action on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6 of U.S.

Patent No. 6,468,998. Applicant's arguments have been found to be persuasive, and the rejection is withdrawn.

Claim Objections

Claims 1-17 and 21-23 are objected to for containing elected and non-elected subject matter. The elected subject matter is described in the previous action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 and 16 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant application, compounds of Formula I are claimed with L¹ and L² are recited to be C₁-C₁₀ optionally substituted alkylene or C₂-C₁₀ optionally substituted alkenylene, wherein one or more said C is optionally replaced by a heteroatom selected from N, O, or S, or further substituted with =O, or both.

The specification fails to teach compounds covering the entire scope of the claimed invention. For example, the depicted species in Figure 1 do not show any instances of a linking group carbon being replaced by N, O, or S. Hence, the working examples in the specification do not cover a representative number of compounds to

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cover the entire invention as claimed. Therefore, a person of skill in the art would deem that the Applicant did not possess the entire invention as claimed at the time of filing, and claims 1-14 and 16 do not meet the written description portion of 35 U.S.C. 112, first paragraph. Applicant is encouraged to limit the substituent groups to be consistent with those fully supported by the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

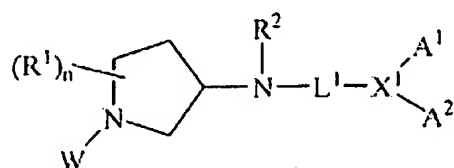
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

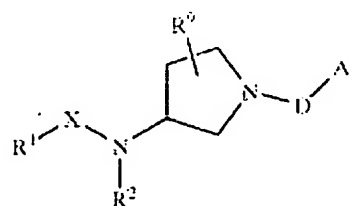
Claims 1-16 and 23 rejected under 35 U.S.C. 103(a) as being unpatentable over Kuroita et al. (USPN 6,468,998).

The instant application claims compounds of the formula



where: W is L²-A³; L¹ and L² are optionally substituted C₁-C₅ alkylene with no carbons replaced by a heteroatom; A¹, A², and A³ are phenyl; X¹ is CR³; and all other substituents are as defined.

Determination of the scope and content of the prior art (MPEP §2141.01)



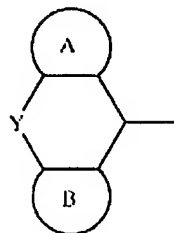
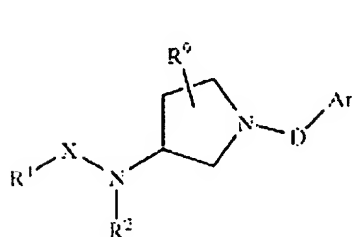
Kuroita et al. teach compounds of the formula with substitutions as defined. See column 2, lines 34 through column 4, lines 65. Kuroita et al. also teach the pharmaceutical composition. See column 5, lines 50-53.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Kuroita et al. do not teach specifically the compounds of the instant invention.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Kuroita et al. teach generally compounds with the base formula:



in which X is C(O); R₁ is

, Y is absent, A, B,

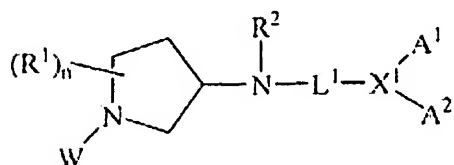
and Ar are phenyl groups, D is an optionally substituted linear alkylene chain having 1 to 8 carbon atoms, and all other substituents are as defined.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to follow the synthetic scheme of Kuroita et al. and make the claimed invention with a reasonable expectation of success. The motivation to do so is provided by Kuroita et al. Kuroita et al. teach the use of the synthesized compounds to antagonize 5-HT₂ to treat glaucoma and other ailments. See column 17, lines 51-63.

Thus, the claimed invention as a whole was *prima facie* obviousness over the combined teachings of the prior art.

Claims 17 and 21-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Kuroita et al. (USPN 6,468,998) in view of In re Henze, 85 USPQ 261 (1950).

The instant application claims compounds of the formula

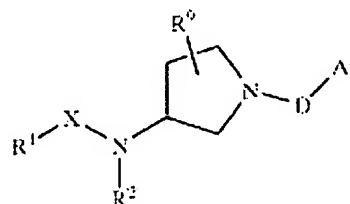


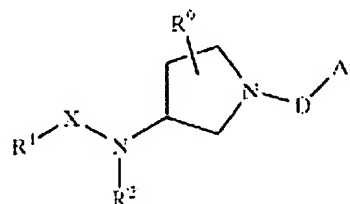
where: W is L²-A³; L¹ and L² are optionally substituted

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C₁-C₅ alkylene with no carbons replaced by a heteroatom; A¹, A², and A³ are phenyl; X¹ is CR³; and all other substituents are as defined.

Determination of the scope and content of the prior art (MPEP §2141.01)



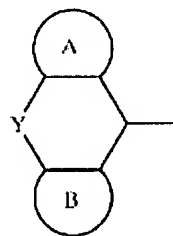
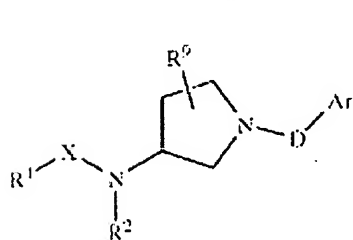
Kuroita et al. teach compounds of the formula  with substitutions as defined. See column 2, lines 34 through column 4, lines 65. Kuroita et al. also teach the pharmaceutical composition. See column 5, lines 50-53.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Kuroita et al. do not teach specifically the compounds of the instant invention.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Kuroita et al. teach generally compounds with the base formula:



in which X is C(O); R₁ is

, Y is absent, A, B,

and Ar are phenyl groups, D is an optionally substituted linear alkylene chain having 1 to 8 carbon atoms, and all other substituents are as defined.

To those skilled in chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. In

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re Henze, 85 USPQ 261 (1950). In the instant case the one carbon linker for L¹ is a homologue of a 3-6 carbon linker. They are expected by those of skill in the art to act in the same fashion unless unexpected results are presented. These unexpected results should be show that the modification to Kuroita et al.'s compounds would not fulfill their method of use to antagonize 5-HT₂ or that Kuroita et al.'s compounds do not fulfill the purpose of the instantly claimed compounds.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to follow the synthetic scheme of Kuroita et al. and make the claimed invention with a reasonable expectation of success. The motivation to do so is provided by Kuroita et al. Kuroita et al. teach the use of the synthesized compounds to antagonize 5-HT₂ to treat glaucoma and other ailments. See column 17, lines 51-63.

Thus, the claimed invention as a whole was *prima facie* obviousness over the combined teachings of the prior art.

Conclusion

Claims 1-17 and 21-23 are rejected. Claims 1-17 and 21-23 are objected to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

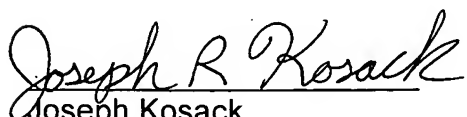
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

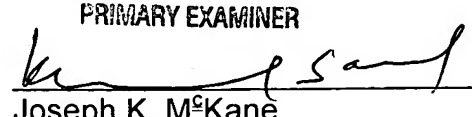
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Kosack whose telephone number is (571)-272-5575. The examiner can normally be reached on M-F 5:30 A.M. until 2:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^cKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Joseph Kosack
Patent Examiner
Art Unit 1626

KAMAL A. CAEED, PH.D.
PRIMARY EXAMINER

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Supervisory Patent Examiner
Art Unit 1626